MICHIGAN
BRAIN &SPINE
INSTITUTE

November 30, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom This Letter Presents:

This is a letter in‘reference to **Docket** No. **97N-484S.** It is a physician comment regarding the efficacy and safety of the use of allograft bone dowels as medical implant devices.

We have had a little over one year experience utilizing allograft bone dowels as medical devices in approximately 72 cases. To date there has been no failure of the device *in vivo.* Specifically, we have not seen any fatigue fracturing or disintegration of the bone dowel device to date. There has been good maintenance of the intravertebral body disc space height with very little subsidence. It is too early to comment on fusion rates, though they are at least comparable to, if not better than, metal implant cylindrical devices.

There are several *in vivo* clinical trials currently ongoing comparing bone dowel implants to metal implant devices. We are presently involved in such a trial and have noted no significant difference between the two. We think it would be practical and prudent for the FDA to review and utilize these current clinical trials to determine safety issues rather than subjecting bone banks to premarket trial requirements, the sponsoring of clinical trials, and submitting lengthy regulatory documentation for a product that’s already in the *in vivo* stages of utilization.

We are happy to meet and/or discuss with anyone the efficacy of utilizing bone dowels and/or metal devices for interbody fusion techniques.

Sincerely,

Jason A. Brodkey, M.D.

JAB/leo (d: 113099 t: 113099)

cc: E. Ron Pickard
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